

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In the Patent Application of: Edward Vaquero, et al.  
Serial No.: 10/813861  
Confirmation No.: 5583  
Filed: March 31, 2004  
For: IOL INJECTOR  
Examiner: Tuan Van Nguyen  
Art Unit: 3731

**APPEAL BRIEF**

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P.O. Box 1450  
Commissioner for Patents  
Alexandria, Virginia 22313-1450

Sir:

By Notice of Appeal filed on September 14, 2009, Applicant appeals the Final Rejection in the above-identified application, and submits this Brief in support thereof. Please charge the fee under 37 CFR 1.17(c) to Deposit Account No. 02-1425. No additional fee is believed to be due. However, please charge any additional fees or credit overpayment to Deposit Account No. 02-1425.

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**I. Real Party in Interest**

The real party in interest in this appeal is Bausch & Lomb Incorporated, as evidenced by the Assignment recorded at Reel 015073, Frame 0608.

**II. Related Appeals and Interferences**

Applicant is not aware of any other appeals or interferences which will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

**III. Status of Claims**

Claims were objected to because there are two claims numbered 25.

Claims 25, 25, 26 and 28-30 were objected to as dependent from claim 1 which is now cancelled.

Claims 13-15, 18-23 and 25-30 are pending, with claim 13 being the only independent claim.

Claim 24 is withdrawn.

Claims 1-12, 16 and 17 were cancelled.

Claims 13-15, 18-23, 25, 26 and 28-30 were rejected under 35 U.S.C. 103 over U.S. Patent No. 6,491,697 to Clark (hereinafter "Clark") in view of U.S. Patent No. 6,010,510 to Brown (hereinafter "Brown").

Claim 27 was rejected under 35 U.S.C. 103 over Clark in view of Brown and further in view of U.S. Patent No. 6,447,520 to Ott (hereinafter "Ott").

**IV. Status of Amendments**

No amendments have been filed following the Final Rejection of November 28, 2008.

**V. Summary of Claimed Subject Matter**

Independent claim 19 recites an injector for delivering a foldable IOL into an eye (r.n. 10 in FIG. 1A; [0019] lines 1-2). The injector comprises an injector body (r.n. 12 in FIG. 1A; [0019] lines 2-3). The injector body has a tip (r.n. 18 in FIGs. 1A and 2; [0019] line 8 and [0024]). (Note – paragraph [0024] was amended on page 2 of the Applicants' Reply to Office Action mailed on September 24, 2007). The tip comprises a first segment (r.n. S<sub>2</sub> in FIGs. 2-4;

[0009] lines 7-9 and [0024] lines 9-11), a second segment (r.n. S<sub>3</sub> in FIGs. 2-4; [0009] lines 13-14 and [0024] line 17-18) and a third segment (r.n. S<sub>4</sub> in FIGs. 2-4; [0009] lines 16-18 and [0024] line 18-19), the third segment extending to an open end of the injector body (r.n. 18a in FIGs. 2-6; [0009] lines 16-18 and [0024] line 20). The open end is adapted to permit the IOL to exit the injector into the eye ([0008] lines 14-15 and [0024] line 20). At least one slot extends from the open end through the second segment and the third segment (r.n. 21a in FIGs. 2 and 3; [0025] lines 1-2). The third segment is connected to the second segment at a transition point (T<sub>3</sub> in FIGs. 2-6; [0024] lines 20-21). The transition point is characterized by a change in taper (FIG. 2-6; [0024] lines 17-20).

Dependent claim 25 recites that the change in taper is a discrete change in taper (FIG. 2-6; [0024] lines 17-20).

#### **VI. Ground of Rejection to be Reviewed on Appeal**

The grounds of rejection raised by this appeal are:

- 1. Whether claims 13-15, 18-23 and 25-30 were improperly rejected under 35 U.S.C. §103(a) over Clark in view of Brown.*
- 2. Whether claim 27 was improperly rejected under 35 U.S.C. §103(a) over Clark in view of Brown as applied to claim 13, and further in view of Ott.*

## **VII. Argument**

### **1. Preliminary Matters**

As indicated above, there are two pending claim that are numbered claim 25. There are no arguments below related to the subject matter of either claim numbered 25. For discussions below, the first claim 25 will be referred as 25 and the second claim will be referred to as claim 25'.

The Applicants will, after this Appeal, renumber the second claim 25 as claim 26, and increment every claim thereafter by one number. Additionally, current claim 27 (which will be renumbered as claim 28) will be amended to depend from claim 27.

The Examiner, in the Office Action, has correctly assumed that claims 25, 25', 26 and 28-30 were intended to depend from claim 13.

The Applicants will, after this Appeal, amend claims 25, 25', 26 and 28-30 to depend from claim 13.

### **2. Claims 13-15, 18-23 and 25-30 were improperly rejected under 35 U.S.C. §103(a) over Clark in view of Brown.**

#### **A. Discussion of the Cited Prior Art**

Clark discloses an instrument for inserting a flexible intraocular lens into an eye (Abstract, lines 1-2). The instrument includes a compressor for laterally compressing the lens into a small cross-sectional configuration to pass the lens through a narrow incision (Abstract, lines 2-5). The compressor includes retainers along the interior of the inserter to maintain the side edges of the lens in a substantially planar orientation during compression (Abstract, lines 5-8). The free end of the instrument is provided with a pair of opposed longitudinal slits 121 (col. 6, lines 31-33). The slits 121 are wide enough to permit sides of the optic to extend beyond the exterior sides of the cannula 28 (col. 6, lines 33-35). Clark discloses that slits permit lateral expansion of the lens prior to release of the lens into the eye (col. 6, lines 35-36). Clark further discloses that the natural resilient force which biases the lens to assume its original uncompressed shape is dissipated in a controlled environment of the cannula (col. 6, lines 37-39). Clark also discloses that cannula 28 includes a proximal funnel-shaped portion 103 which tapers

to compress the lens, and an elongate distal portion 105 which directs the compressed lens into an eye.

As shown in each of FIGs. 2, 3, 11 and 12 of Clark, the slit 121 extends only along distal portion 105 (which has only a single taper), and not along funnel-shaped portion 103.

Brown is directed primarily to an intraocular lens plunger having a blunt, rounded tip that is offset from the center line of the plunger rod (Abstract, lines 1-2). Brown discloses that such a configuration assures that the tip is biased downward against the bottom of the cartridge bores (Abstract 2-4). Brown states that such biasing helps prevent the tip from riding up over the IOL and thereby being folded within the IOL (Abstract, lines 4-6). Brown discloses an injector segments having different taper (e.g., see FIG. 4).

The injector of Brown does not include any slits or slots.

**B. Claims 13-15, 18-23 and 25-30 were improperly rejected under 35 U.S.C. §103(a) over Clark in view of Brown because none of the art of record discloses “[a] slot extending from [an] open end through [a] second segment and [a] third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper” and the Examiner’s rationale for modifying Clark to include such a configuration is insufficient**

The Examiner alleges that Clark discloses all elements of claim 13 except a second segment connected to a third segment at a transition point, the transition point characterized by a discrete change in taper. However, the Examiner alleges that Brown discloses, in FIG. 4, an IOL injector comprising, a tip comprising a third segment having a constant diameter, a second segment having a taper located on the outer surface and a taper located on the inner surface of bore 16. The Examiner further alleges that it would have been obvious to one of ordinary skill in the art to optimize the lengths of slots 121 to extend through the second segment to ensure that the IOL gradually returns to its original shape before being released into the eye to avoid complications of injuring the eye. The Applicants respectfully disagree with some of the Examiner’s allegations and disagree that claim 13 is obvious in view of the cited art.

The Applicants agree that Clark fails to disclose “An injector ... comprising ... at least one slot extending from the open end through the second segment and the third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper.” Furthermore, none of the art of record shows a transition point having a change in taper, as recited in claim 13. The Applicants further point out that Brown does not disclose a slot of any kind extending from the open end.

The Applicants address the Examiner’s allegation that it would have been obvious to one of ordinary skill in the art to optimize the lengths of slots (i.e., “slits 121” of Clark) to extend through a second segment of an apparatus formed by a combination of the apparatus of Clark and Brown to ensure that the IOL gradually returns to its original shape before being released into the eye to avoid complications.

The Applicants do not deny slots were known. In fact, even Clark discloses that the slits 121 (i.e., slots) permit lateral expansion of the lens prior to release into the eye (col. 6, lines 35-36). Clark further discloses that, as a result of such expansion, the natural resilience which biases the lens to assume its original uncompressed shape is dissipated in the controlled environment of the cannula (col. 6, lines 37-38 of Clark). However, neither Clark nor Brown discloses “An injector ... comprising ... at least one slot extending from the open end through the second segment and the third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper,” as recited in claim 13. In fact Clark shows a slot extending across only a single segment, with no change in taper.

Regarding the Examiner’s allegation that it would have been obvious to one of ordinary skill in the art to optimize the lengths of slots 121 to extend through the second segment to ensure that the IOL gradually returns to its original shape before being released into the eye to avoid complications, the Applicants note that none of the art of record suggests such a configuration. Rather, as stated above, Clark discloses a slot that extends into a single segment. Significantly, Clark teaches that such a configuration (without any modification) achieves the result that the Examiner sets forth as the rationale for modifying Clark (i.e., gradual return of the IOL to its original shape before it is released into the eye). Accordingly, the Examiner’s rationale for modification is without merit.

Furthermore, the Examiner's allegation that modifying the slot of Clark is "an optimization" is without support from any of the art of record. In fact, as stated above, the Examiner's alleged motivation for modifying the slot of Clark (i.e., to ensure that the IOL gradually returns to its original shape before being released into the eye to avoid complications of injuring the eye) can be achieved with the slot as described in the prior art slit where the slot extends over only a single segment.

Additionally, there is nothing of record that suggest that a reasonable expectation of success exist if the slot is extended from the open end through the second segment and the third segment across a transition point characterized by a change in taper.

Accordingly, there is no teaching of the modification (i.e., optimization) to Clark as proposed by the Examiner and there is no rationale for making such a modification to Clark. It is worth mentioning that the reason set forth in the Specification of instant application for the slot configuration as recited in claim 1 (i.e., providing a doctor with options for anchoring the tip of the inserter in the eye during injection of a lens" (see page 12, line 13 et seq. of the present application)) is entirely different than any reason set mentioned in Clark or Brown.

For the above reasons, claim 13 is patentable over the combination of Clark and Brown.

Claims 14, 15 and 18-23, 25-31 depend from claim 13 and are patentable for at least the same reasons as claim 13. Withdrawal of the rejections of claims 13-15, 18-23 and 25-31 is respectfully requested.

**3. Claim 27 was improperly rejected under 35 U.S.C. §103(a) over Clark in view of Brown and further in view of Ott.**

**A. Discussion of the Cited Prior Art**

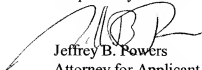
Ott discloses an IOL inserter including a cartridge. The cartridge has segments having different tapers (e.g., see FIG. 4A). Ott does not disclose an inserter having any slots or slits.

Ott does not cure the deficiencies of the combination of Clark and Brown as set forth above. Accordingly, claim 27 is patentable over any combination of Clark, Brown and Ott.



In light of the foregoing arguments, applicants request that the outstanding rejection be reversed and that the pending claims 13-15 and 18-24, 26-31 be allowed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'JBP', is written over the printed name of Jeffrey B. Powers.

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## **VIII. Claims Appendix**

**The claims under appeal are as follows:**

### **LISTING OF CLAIMS:**

1-12. (Cancelled)

13. An injector for delivering a foldable IOL into an eye, comprising:

an injector body having a tip comprising a first segment, a second segment and a third segment, the third segment extending to an open end of the injector body, the open end being adapted to permit the IOL to exit the injector into the eye,

at least one slot extending from the open end through the second segment and the third segment, the third segment connected to the second segment at a transition point, the transition point characterized by a change in taper.

14. The injector of claim 23, wherein the constant outer diameter is about 2.0 to 2.5mm.

15. The injector of claim 13, wherein the open end has a slanted face.

16-17. (Cancelled)

18. The injector of claim 13, wherein the at least one slot comprises at least two slots.

19. The injector of claim 18, further comprising a lumen extending through the tip, and two lumen grooves extending along the lumen, each of the slots collinearly extending from a corresponding one of the lumen grooves.

20. The injector of claim 19, further comprising a compressor drawer extending from a loading bay of the injector body, the drawer movable between an open position and a closed position.

21. The injector of claim 20, wherein the compressor drawer comprises a drawer groove.

22. The injector of claim 21, wherein the drawer groove is aligned with one of the lumen grooves.
23. The injector of claim 13, wherein the third segment has a constant outer diameter.
24. A method of injecting a foldable IOL into an eye, comprising:  
providing an injector body having a tip comprising (i) a first segment, (ii) a second segment, the second segment extending to an open end of the injector body, the open end being adapted to permit the IOL to exit the injector into the eye, and (iii) at least one slot extending from the open end through the first segment and the second segment, the second segment connected to the first segment at a transition point, the transition point characterized by a discrete change in taper;  
inserting the tip into an eye up to the transition point; and  
delivering the IOL into the eye while maintaining the tip in the eye up to the transition point.
25. The injector of claim 1, wherein the change in taper is a discrete change in taper.
25. The injector of claim 1, wherein the first segment is unslotted.
26. The injector of claim 1, wherein the first segment has a different taper than the second segment.
27. The injector of claim 26, wherein the second segment has a constant outer diameter.
28. The injector of claim 1, wherein the first segment is configured to compress a lens transported therethrough.

29. The injector of claim 1, wherein the second segment has a greater taper than the third segment.
30. The injector of claim 1, comprising a second transition point between the first and the second segments, an outer diameter at the second transition point being larger than an outer diameter at the transition point between the third segment and the second segment.

**IX. Evidence Appendix**

(None)

**X. Related Proceedings Appendix**

(None)